



SOMERVILLE BOARD OF HEALTH

Rules and Regulations Governing Variances Granted to Utilize Reduced Oxygen Packaging of Food in Food Establishments

The City of Somerville Board of Health hereby orders that the following regulations be and are hereby adopted on June 18, 2015 to become effective on June 22, 2015.

Authority. These rules and regulations are adopted under the authority of Section 31 of Chapter 111 of the Massachusetts General Laws.

Purpose. The use of reduced oxygen packaging (hereinafter ROP) has the potential for growth of serious foodborne pathogens such as *Clostridium botulinum* and *Listeria monocytogenes*, resulting in a public health risk. The purpose of these regulations is to ensure that ROP process is designed by a knowledgeable person and implemented in a safe manner that does not create a risk of illness from these pathogens.

Scope. The scope of these regulations applies to any variance granted by the Board of Health after the effective date of these regulations approving the use of ROP, as defined by the 1999 Federal Food Code, §1-201.10(67) (a) and (b).

These regulations also designate the requirements for the renewal of a variance granted as well as grounds for the suspension or revocation of a variance.

Variance Requirements. A food establishment shall obtain a variance from the regulatory authority as specified in § 8-103.10 and under § 8-103.11 of the Federal Food Code in effect under 105 CMR 590.000 (hereinafter the Food Code) for packaging food using a ROP method except as specified under § 3-502.12 where a barrier to *Clostridium botulinum* in addition to refrigeration exists; custom processing animals that are for personal use as food and not for sale or service in a food establishment; or preparing food by another method that is determined by the regulatory authority to require a variance.

ROP Criteria. (§3-502.12 of the Food Code: Reduced Oxygen Packaging Criteria)

(A) Except for a food establishment that obtains a variance as specified under § 3-502.11 of the Food Code, a food establishment that packages food using a reduced oxygen packaging method

and *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form shall ensure that there are at least two barriers in place to control the growth and toxin formation of *C. botulinum*,

(B) A food establishment that packages food using a reduced oxygen packaging method and *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form shall have a Hazard Analysis Critical Control Point (HACCP) plan that contains the information specified under ¶ 8-201.14(D) of the Food Code and that:

- (1) identifies the food to be packaged;
- (2) Limits the food packaged to a food that does not support the growth of *Clostridium Botulinum* because it complies with one of the following:
 - (a) Has an a_w of 0.91 or less,
 - (b) Has a pH of 4.6 or less,
 - (c) Is a meat or poultry product cured at a food processing plant regulated by the U.S.D.A. using substances specified in 9CFR 318.7 Approval of substances for use in the preparation of products and 9CFR 381.147 Restrictions on the use of substances in poultry products and is received in an intact package, or
 - (d) Is a food with a high level of competing organisms such as raw meat or raw poultry;
- (3) Specifies methods for maintaining food at 5°C (41°F) or below;
- (4) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:
 - (a) Maintain the food at 5°C (41°F) or below, and
 - (b) Discard the food if within 14 calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;
- (5) Limits the shelf life to no more than 14 calendar days from packaging to consumption or the original manufacturer's "sell by" or "use by" date, whichever occurs first;
- (6) Includes operational procedures that:
 - (a) Prohibit contacting food with bare hands,
 - (b) Identify a designated area and the method by which:

(i) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination, and

(c) Delineate cleaning and sanitization procedures for food-contact surfaces; and

(7) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:

(a) Concepts required for a safe operation,

(b) Equipment and facilities, and

(c) Procedures specified under Subparagraph (B) (6) of this section and § 8-201, 14(D) of the Food Code.

(C) *Except for fish that is frozen before, during, and after packaging*, a food establishment may not package fish using a reduced oxygen packaging method.

Substantially Different ROP Operations. The establishment shall apply for individual variances for ROP operations that have packaging methods which are substantially differ from one another.

Qualified Consultant Required: Due to the public health risk associated with ROP, the Board of Health requires a knowledgeable person to prepare the plan, train the staff, and conduct an annual review and refresher training for personnel when any food establishment is granted an ROP variance. The manager of a food establishment seeking a variance for ROP shall submit a HACCP plan prepared by a consultant who either is on the Massachusetts Department of Public Health Food Protection Program's List of Massachusetts Food Protection Manager Certification Exam and Trainer Directory or whose credentials and experience are considered equivalent and appropriate qualifications ("Qualified Consultant") by the agent of the Somerville Board of Health.

ROP Operations Audit: Upon the granting of the variance for ROP by the Board of Health, a Qualified Consultant shall conduct an audit of the initial implementation of the plan to determine if the establishment properly follows its provisions. The consultant shall certify to the Board of Health that the ROP operation meets the requirements of the plan within thirty (30) days of variance issuance.

Variance in Writing. Any variance granted by the Board of Health shall be in writing. A copy of any such variance shall, while it is in effect, be available to the public at all reasonable hours in the office of the clerk of the city or town, or in the office of the Board of Health. Copies of all variances shall be provided to the Director upon request.

Enforcement; Qualification, revocation or suspension of a variance. Any variance may be subject to such qualification, revocation, or suspension as the Board of Health expresses in its grant. A variance may otherwise be revoked, modified, or suspended, in whole or in part, only after the holder thereof has been notified in writing and has been given an opportunity to be

heard in conformity with the requirements for an order and hearing in 105 CMR 590.015. Notwithstanding the above, the establishment, and any variance, is subject to the Board of Health's authority for summary suspension of permit/emergency closure without a prior hearing, as provided in 105 CMR 590.014(A). The Board of Health shall have the authority to enforce this regulation through any legal means, including the use of violation notices, cease and desist orders, administrative orders, and/or civil and criminal court actions.

Annual Renewal of Variance. The establishment shall apply for a renewal annually at least thirty (30) business days prior to the expiration date of the granted variance. The renewal request shall be made on a form provided by the Board of Health.

Annual ROP Audit. The establishment shall have a Qualified Consultant conduct an audit of the operation of the variance procedures within thirty (30) days of the variance renewal, and shall report in writing the results of that audit to the agent of the Board of Health within thirty (30) days of renewal.

Severability. If any paragraph or provision of this regulation is found to be illegal or against public policy or unconstitutional, it shall not affect the legality of any remaining paragraphs or provisions.

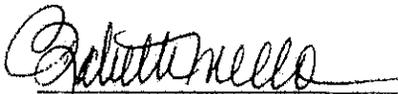
Fine for Violation. Any person who violates any provision of this regulation shall be issued a warning and order to correct for the first offense, and a fine of \$100 for the second or subsequent offense. A ROP variance may be subject to revocation by the Board for a second or subsequent offense. Each day that a violation continues shall be deemed to be a separate offense.

Non-Criminal Disposition. Whoever violates any provision of this regulation may be penalized by the non-criminal method of disposition as provided in General Laws, Chapter 40, Section 21D or by filing a criminal complaint at the appropriate venue. Enforcement of this regulation shall be by the Somerville Board of Health or its designated agent(s).

Regulations Adopted by Board of Health on: June 18, 2015



Brian Green, MD, Board Chairperson



Babette Mello, Board Member



Paula Machado, Board Member